UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

DARELL COWEN,

Plaintiff,

v.

Case Number 05-10307-BC
Honorable Thomas L. Ludington

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant.
_____/

ORDER GRANTING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Darrell Cowen[1] twice had a penile prosthesis implanted. Defendant American Medical Systems, Inc. marketed and manufactured that device, the Ambicor Penile Prosthesis. Plaintiff subsequently had each product explanted. Plaintiff then filed a complaint alleging a design defect in Defendant's product. Defendant moved for summary judgment, to which it is entitled because 21 U.S.C. § 360k(a) preempts Plaintiff's claim and because Plaintiff has failed to demonstrate the existence of a material issue of fact on his claim of a design defect under Mich. Comp. Laws § 600.2946.

Defendant's product, a dual cylinder and pump device, permits inflation and deflation that controls whether the penis is erect or flaccid. Defendant's product is a Class III medical device under 21 U.S.C. § 360c(a)(1)(C). The Food and Drug Administration (FDA) granted approval of Defendant's product on July 18, 2000, after Defendant completed a product development protocol (PDP), as described in 21 U.S.C. § 360e(c) & (f).

[1]References to Plaintiff are in the singular, because his the claim of his wife, Teressa Cowen, for loss of consortium is derivative.

On October 31, 2001, Plaintiff had the first prosthesis implanted. On May 12, 2003, Plaintiff had the product explanted after he experienced pain when operating the prosthesis and after a urologist concluded that the pump had lost fluid. During that same surgery, Plaintiff had a second prosthesis implanted. On May 24, 2003, after a visit to the emergency room for a post-operative infection, Plaintiff had the second penile prosthesis explanted.

On November 24, 2004, Plaintiff filed suit for a defect in design, and Defendant later removed the case to this Court. Defendant filed a motion for summary judgment, asserting, *inter alia*, that 21 U.S.C. § 360k(a) preempted Plaintiff's claims and that Plaintiff has not shown that genuine issues of material fact remain regarding the design of Defendant's product under Mich. Comp. Laws § 600.2946. In response to Defendant's motion for summary judgment, Plaintiff provided several documents pertaining to Defendant's internal corporate decisions regarding the design of the product. Plaintiff provided no evidence or expert to criticize Defendant's product design or to demonstrate the availability of an alternative design.

21 U.S.C. § 360k(a)[2] expressly provides for preemption of some state laws. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court ruled that § 360k(a) did not preempt at least some state law claims. A court must carefully compare "the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within

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[2]21 U.S.C. § 360k(a) provides:

> General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
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> (1) which is different from, or in addition to, any requirement applicable to the device under [21 U.S.C. § 301 *et seq*.], and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [21 U.S.C. § 301 *et seq*.].

the intended preemptive scope of the statute and regulations." *Id*. at 500 (footnote omitted). *See also Kemp v. Medtronic, Inc*., 231 F.3d 216, 223-228 (6th Cir. 2000) (scrutinizing the particulars of a product, the relevant FDA approval process, and those plaintiffs' precise claims to conclude that § 360k(a) preempted claims of negligence per se and failure to warn); *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005) ("Any claim, under state law [of failure to warn] beyond warnings required by the FDA . . . or [of failure to recall] would constitute state requirements 'different from' or 'in addition to' the requirement of the federal [approval process]."). Although some Sixth Circuit cases involved the premarket approval process by the FDA under 21 U.S.C. § 360e, the FDA treats that process as equivalent with the process completed by Defendant, the PDP process. 21 C.F.R. § 814.19.[3] Thus, completing the PDP process demonstrates the FDA's conclusion that it has received "reasonable assurance" of the safety of a device. *See* 21 U.S.C. § 360e(d)(2).

Here, the FDA approved Defendant's product using the PDP process. At the hearing, Plaintiff's counsel stated that the only claim was of a design defect. The FDA approval of Defendant's product through the PDP process represents the FDA's conclusion that it has received "reasonable assurance" of the product's safety. To permit a jury verdict in favor of Plaintiff for a design defect would impliedly require more of Defendant than what the FDA already required. Accordingly, such requirements would be "different from" or "in addition to" those set forth by the FDA and, so, in violation of § 360k(a). Thus, Plaintiff's claim is preempted by § 360k(a), entitling Defendant to judgment as a matter of law sufficient to grant summary judgment.

[3]21 C.F.R. § 814.19 provides, "A class III device for which a product development protocol [PDP] has been declared completed by FDA under this chapter will be considered to have an approved PMA."

Product liability actions in Michigan are governed by Mich. Comp. Laws § 600.2946.[4] The elements of a claim of a design defect are as follows: (1) that the severity of the injury was foreseeable by the manufacturer; (2) that the likelihood of occurrence of her injury was foreseeable by the manufacturer at the time of distribution of the product; (3) that there was a reasonable alternative design available; (4) that the available alternative design was practicable; (5) that the available and practicable reasonable alternative design would have reduced the foreseeable risk of harm posed by defendant's product; and (6) that omission of the available and practicable reasonable alternative design rendered defendant's product not reasonably safe. *See Hollister v. Dayton Hudson Corp.*, 201 F.3d 731, 738 (6th Cir. 2000).

Here, Plaintiff has not designated specific facts by which a jury could find in his favor. He has not identified an expert who has criticized the design of Defendant's product. He has not offered any evidence to show that "a practical and technically feasible alternative production practice was

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[4]Mich. Comp. Laws § 600.2946(2) provides:

> In a product liability action brought against a manufacturer or seller for harm allegedly caused by a production defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product was not reasonably safe at the time the specific unit of the product left the control of the manufacturer or seller and that, according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others." Plaintiff has not shown the viability of an alternate design because Defendant's internal documents, Plaintiff's only record support, reveal only a design option, not the design's usefulness or superiority over other designs. Plaintiff has also not demonstrated the economic feasibility of any alternate design. Plaintiff bears the burden of proof, but he has not demonstrated the existence of an issue of fact on essential elements to show a design defect in Defendant's device. *See Davis v. McCourt*, 226 F.3d 506, 511 (6th Cir. 2000). Thus, summary judgment for Defendant is warranted on this basis as well.

Accordingly, it is **ORDERED** that Defendant's motion for summary judgment [dkt #35] is **GRANTED**.

It is further **ORDERED** that Defendant's motion to strike Plaintiff's response to its motion for summary judgment [dkt #43] is **DENIED** as moot.

s/Thomas L. Ludington
THOMAS L. LUDINGTON
United States District Judge

Dated: December 7, 2006.

PROOF OF SERVICE

The undersigned certifies that a copy of the foregoing order was served upon each attorney or party of record herein by electronic means or first class U.S. mail on December 7, 2006.

s/Tracy A. Jacobs
TRACY A. JACOBS